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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CROMPTON, SEAGER & TUFTE, LLC				
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EXAMINER				
HOUSTON, ELIZABETH				
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10/06/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,168

Applicant(s)

VARDI ET AL.

Examiner

ELIZABETH HOUSTON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 13-17, 19-23 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 13-17, 19-23, 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/19/07, 09/25/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Drawings

2. The drawings are objected to because: new Figure 2 filed on 11/19/07 does not clearly depict the main guidewire lumen with element 35. Additionally, with respect to Figure 2, examiner requests clarification as to whether the distal shaft is attached only at the bond area 23 in this figure or whether the shaft is attached along the length of the inflation tube. The drawing is unclear.

3. The specification states that Fig. 2 illustrates "Bond portion 24 is a three-way bond, connecting one portion of tubing (inflation tube 22) on the proximal end of bond portion 24 and two portions of tubing (inflation tube 22 and a distal shaft 26) on the distal end of bond portion 24," as is claimed in claim 28. However it is unclear what in figure 2 delineates the bond. There is no showing of a proximal end of a bond portion or a distal end of a bond portion.

4. It is unclear in Figure 4 where the bond between the distal shaft and the inflation tube occurs. If the drawing is depicting the claimed invention that the distal shaft is bonded "only" at the bond, then the bond needs to be completed with a line between the distal shaft and the inflation shaft.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 16 and 17 require that the first tube is attached to the second tube external of the three way bond and along an entire length

of the second tube. However claim 13 from which they depend claim that the first and second tubes are bonded "only" at the three-way bond. There is no disclosure that explains how both of these limitations can exist in the same embodiment.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how a catheter can have both the first and second tube bonded "only" at the three way bond and have both the first and second tube attached external of the three-way bond. For the purposes of examination of claims 16 and 17, the limitation "only at the three way bond" will be interpreted as only *near* the three way bond. It is further unclear how the first tube is attached to the second tube along an *entire length* of the second tube when the second tube extends though the length of the balloon as depicted by the guidewire (36) in figures 5a-6b.
8. Claims 13-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the proximal tube is "terminated at a distal open end" that is "coupled to the proximal open end of the first tube ... and the second tube". The embodiment in figure 2 shows a proximal tube (22) that does not have an open distal end at the bond (24) but rather is enclosed. It also shows that the

proximal tube (22) extends beyond the bond portion to become one of the distal tubes (22).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

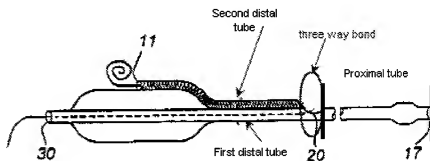
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 4, 13, 14, 16, 17, 19, 21, 22, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ischinger (WO 99/03426).

10. Ischinger discloses a catheter comprising: a proximal tube terminated at a distal open end; a assembly comprising a first tube (channel having main guidewire lumen) terminated at a proximal open end (main exit port) and a second tube (branch guidewire enclosure) terminated at a proximal open end (branch exit port), wherein said first tube is configured to receive a first guidewire and said second tube is configured to receive a second guidewire; and a three-way bond coupling the distal open end of the proximal tube to said proximal open end of said first tube and to said proximal open end of said second tube; wherein the second tube of the distal assembly is bonded to the first distal tube only at (near) the three-way bond. The main exit port is located at a distance from the distal end that is substantially equal to the distance of the branch exit port from the distal end. The distance is less than a distance from the distal to the proximal end of the

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catheter and greater than a distance from the distal end of the catheter to the proximal end of the stent. The proximal end of the bond connects to the distal end of the proximal tube and the distal end of the bond connects to the proximal open end of the first distal tube and the proximal open end of the second distal tube. The second distal tube is detached from the first distal tube outside of the bond (where the second distal tube is attached to the balloon - see below). There is a balloon and inflation lumen. The first tube is attached to the second tube external of the three way bond (between the bond and the balloon - see below) and along an entire length of the second tube (Fig. 1D). The three way bond is a predetermined distance and the proximal tube connects to the three way bond at a location spaced from the distal portion connecting to the three way bond (see below). The guidewires exit at the three way bond.



Claim Rejections - 35 USC § 103

11. Claims 2, 15 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Ischinger in view of Wilson (EP 0 897 700).

12. Ischinger discloses the claimed invention as stated above except for a stent having a side opening and the branch guidewire enclosure positioned through the side opening. Rather Ischinger discloses that the branch guidewire enclosure is proximal of the stent in order to position side branch stents with oblique ends. Wilson discloses a similar invention to Ischinger where the side branch enclosure is proximal of the stent for positioning the stent in a side branch (Fig. 11D). Wilson also discloses embodiments where the side branch enclosure extends through a stent having a sidewall opening for placing a main branch stent across a side branch opening (Fig. 12a-12c). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Ischinger to have a side branch enclosure that extends through a side opening of the stent in order to provide for the delivery of a main branch stent. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

13. Claims 5, 8, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ischinger.

14. Ischinger discloses the claimed invention as stated above except for the dimensions locating the exit openings and the length of the guidewire. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the size of the catheter and therefore the location of the exit ports and length of the guidewire depending on the size and location of the lumen in which it would be used.

For instance catheter used on an infant would be significantly smaller than that used on a large adult. Additionally, a catheter that is being delivered to the aorta will be larger than one that is being delivered to the brain. Such a modification would have involved a mere change in the size of a component, and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 06/19/08 have been fully considered but they are not persuasive. As noted above, the terminology "at" in the limitation "only at the three way bond" or "only at said branch exit port" is broadly being interpreted as *near*. Claims in a pending application should be given their broadest reasonable interpretation consistent with the specification. The words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. See MPEP Chapter 2111.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731